DRAFT FOR HIT POLICY COMMITTEE APPROVAL

June 8, 2011

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Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. Mostashari:

On April 21, 2011, the Adoption and Certification Workgroup (Workgroup) of the Health Information Technology Policy Committee (HITPC) held a one-day hearing on Electronic Health Record (EHR) Usability.

Public comment was solicited both within the hearing and on the Federal Advisory Committee Blog (from April 18 to 29, 2011).

This letter provides a summary of what we heard at the hearing, and identifies areas we would recommend for further exploration. We learned at the hearing that there is a wide range of opinions on where we are, where we could be and how to get there. We offer you our thoughts on "usability as a community journey," exploring what is usability, how is it measured and why is it important. Specifically, we expand on the different contexts in which electronic health records are used and the opportunities to measure and improve usability. The highlights from the hearing are included in the attached summary slides. Transcripts of the hearing and the blog are available.

Overview of Hearing

At the hearing, you asked the Workgroup to consider the following topics:
- Improve understanding on usability issues
- Technology that fully supports care
- Identify and address potential safety issues
- Enable constructive innovation
- Flexible and rigorous options for usability evaluation

To address the topics above, the hearing was organized with five panels, consisting of:
- Care providers
- Consumers
- Technology developers
- Usability researchers
- Market feedback/new technologies

The International Organization for Standardization (ISO) defines usability as "the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use."

There are three key ideas which came up repeatedly in the hearings:
- Specified users
- Specified goals
- Specified context of use

In addition to these three framing concerns, we also heard about the <u>desired outcomes of improved usability</u> (including safety, reduced cost, lower frustration), and a range of <u>attributes of usability</u> (including appearance, workflow, accuracy, access to data). The hearing raised more questions than it provided answers.

Key Issues/Concepts from the usability hearing
1. Multiplicity of Systems
2. Role of Standards or Guidelines
3. Patient-Physician Interaction
4. Cognitive Load
5. Abilities and Disabilities
6. System Configuration
7. Impact of Regulation on Usability, and Testing and Measuring Usability

1. Multiplicity of Systems

One thread throughout the hearing which seems to have direct impact on usability is that of multiplicity – many systems are needed to provide care, whether within a single setting or in multiple settings. Individuals use more than one clinical application. This applied to all the panels. It includes:
- physicians who work in multiple care settings
- clinicians within a single setting that use a variety of systems often from multiple vendors
- patients who receive care in many settings
- vendors that support products configured differently in each customer care setting

Not covered by the hearings, but of concern as we look at the broader goal of continuity of care, are people serving as care coordinators (patients, providers, payors). This role is important to achieving smooth care transitions. These individuals also access multiple EHRs.

One of the open questions is how to bring some degree of consistency to this multiplicity of systems. This is one aspect of "specific context for use." In the real-world of healthcare, EHRs cannot be fully assessed in isolation.

2. *Role of Standards or Guidelines*

A repeated analogy we heard in the hearing is that of the automobile: steering wheel, directional signals, accelerator and brake pedals have a high degree of consistency from vehicle to vehicle. Other aspects of the vehicle's controls and indicator dials vary somewhat but not all that much. Similarly, road signage is consistent for stop signs, informational and warning signs. Although EHRs are significantly more complex than an automobile analogy, they have not reached this level of maturity in basic approach and design. Each has custom "controls" and custom "gauges," and the rules of the road are still being defined.

Some areas which were discussed concerning guidelines that may aid in improving usability include:
- Alerting (specifically addressing alert fatigue)
- Consistency in data location within a screen
- Consistency in data presentation (e.g., flashing red is a concern)
- Existing conventions such as TALLman lettering for distinguish similar sounding drug names
- Definition of a limited set of icons that would be consistent across applications as well as consistent terminology for the actions taken within an EHR.

3. *Patient-Physician Interaction*

As computerized documentation increases within the patient-physician interaction, a frustration voiced was the potential for clinicians to focus more on the computer and less on the patient. We also heard examples of where computer usage enhances the clinical interaction, including validation of the information with the patient and increased levels of patient engagement.

The physical configuration of technology appears to be every bit as important as the logical configuration of the screen design and screen flow. Anecdotes of the success of tablet devices include its flexibility for being viewed together by patient and physician. Additionally, it was stated improved interaction can be facilitated by user training that addresses how to develop a "technology enabled" bedside manner. These examples are further reminders that a successful implementation depends on much more than what is on the computer screen.

4. *Cognitive Load*

We heard about various factors in the design and implementation of EHRs that affect the cognitive load placed on the user (for example, finding information that takes many steps and requires remembering information across many displays – sometimes resulting in information being written down by the clinician as they find it). This is one aspect of the "specific goal" that the user is looking to accomplish.

5. *Abilities and Disabilities*

The hearing raised a variety of concerns related to user abilities and disabilities – whether physician, other staff or patients – there is a wide range of visual, auditory, cognitive and other capabilities. As the system interfaces get more complex, the adaptive tools to support that interface must also adjust. For example, we heard about the problems of screen-readers and other text-to-voice tools dealing with icons and diagrams. These are essential tools for the visually impaired.

We also heard about non-technology solutions, such as the use of assistants who can partner with the primary user or modified workflows that allow for a more team-based approach. The context of usability is not just a single user at a single display screen.

The context is not only display, keyboard and mouse. In addition to tablet devices that are expanding the interface options with multi-touch gestures, we also heard from one vendor with a voice-only interface. The user wears a wireless headset with ear piece and microphone – they hear prompts, answer questions, and are provided with information in response to voice input. Assessing usability in these expanded technologies will be clearly different.

6. *System Configuration*

Many usability issues seem to be associated with the very complexity of the EHR product lifecycle and the subsequent implementation process. The cycle starts with requirements that are built into a product; that product is then tested by the vendor against certification criteria. However, the product is then almost always modified by the customer to configure the software to meet the specific needs of the provider organization.

These requirements result in changes in the systems as implemented.
- Changes in application flow (such as warnings and reason for over-ride)
- Changes in workflow (such as who does the work)
- Changes in data collected for secondary uses (additional questions)
- Greatly expanded answer sets (such as for smoking status or ethnicity)

This complex development and implementation process requires multiple feedback loops: between the users and the implementers within an organization, between the implementers and the vendors to improve the implementation, and within the vendor organization to improve the product.

All of these changes are areas where getting the details right is the difference between a highly successful implementation and a failure. For example, a change in workflow related to warnings during ordering may ask a physician to perform a task previously done by a pharmacist. It may present challenges to the overall logic of an established order set (as when a patient-specific warning occurs while using a standard protocol). It may increase the complexity of the activity (perhaps the drug that needs to be changed is not the one now generating the warning, but a previously prescribed drug).

Adding questions for the user to answer often changes the user's interaction with the system in unforeseen ways. Does the user have the information being asked for? What does it take to acquire the information? Is this the right user to be asking?

Expanding the answer set adds further complexity. As the answers get more granular, the method to select the answer changes, from yes/no, to a short multiple choice list to a large or complex list. Choosing the right answer from among hundreds of options is different from choosing the right one from a handful. The approaches for presenting one set of options are very different from presenting the other. In some cases, the best approach may be to not ask the user to choose but to provide other methods for arriving at the right answer, such as deducing the answer from other data or using "smart" interactive searches that anticipate user input. The hearings did not provide information on how different applications handle these cases.

7. *Impact of Regulations on Usability, and Testing and Measuring Usability*

The ISO model for software system quality includes several aspects only one of which is usability:
- Functionality (including accuracy, suitability, interoperability, compliance, security)
- Reliability (including maturity, fault tolerance, recoverability)
- Usability (including understandability, learnability, operability)
- Efficiency (including time behavior, resource utilization)
- Maintainability (including analyzability, changeability, stability, testability)
- Portability (including adaptability, installability, conformance, replaceability)

Many of these aspects were discussed during the hearing and perhaps the broader heading of system quality better covers what the various panelists were addressing. As focused measures of usability are developed, the scope of the measure should be clearly indicated. This will hopefully avoid some of the confusion present during the hearing when panelists were describing different things.

Other differences among panelists on usability testing seemed a result of the different use cases they described as important– which aspects of who, what and context should be measured. That said, there was an overall frustration from providers and consumers since their expectations are higher than what is currently being delivered.

Regulation drives change in systems. ONC and other government agencies have an affect on usability as another source of requirements for EHRs.

Regulatory factors that affect usability include:
- Certification requirements
- Patient/third-party billing
- Quality reporting
- Public health reporting

- Security measures

Regulation can increase the complexity of an application and can also shift the work from one group of individuals to another. Many regulations change the data needed for subsequent activity and these place a burden on the care process. For example, additional detail to support quality measures and to document the level of service for billing increases the burden on clinicians. Depending on how the changes are implemented, there will be varying effects on usability. Some of these consequences are intended but many are not.

During the hearings, we heard the need to have usability testing based on real-world scenarios rather than functions in isolation. Measuring usability requires constraining the specific user, the specific goal and the specific context. Given the wide range covered by EHRs, this requires selecting key use cases and then building usability tests based on these use cases.

We suggest that ONC and the Adoption-Certification Workgroup continue to explore some of these topics, specifically identify a few high-value use cases, particularly those that have safety implications.

Moving Forward

It is clear that usability is important to successful EHR adoption and to achieving the overall goals for health information technology to support improved care. It is also a complex area that will require careful action.

EHR usability has an effect on patient safety. Further work is needed to understand what makes one EHR safer than another, or what makes one design option safer than another.

We suggest development of guidance for providers, possibly through the experience of the Regional Extension Centers, on issues as varied as user training and physical mock-ups of workstation configuration and placement.

We also suggest assessing the effect of regulations on usability. Reviewing the Stage 1 Meaningful Use requirements suggests potential increased data collection, changes in workflow and possible standardization of terminology. These are all likely to affect usability. However, given the complexity and variability of EHRs we do not believe it is currently possible to measure the usability impact of the Meaningful Use requirements in the abstract.

Given how much is still to be learned, we suggest an initial emphasis on the identification of key use cases and desired outcomes. This will provide the context for measuring usability, allowing usability testing and process improvement to proceed.

The Workgroup respectfully submits this letter hoping that it will assist ONC in the important work of improving EHR usability.

Sincerely yours,

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Workgroup

Larry Wolf
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